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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/181,027	10/27/98	HAAF	T A-65680-4/RF

(H)

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EXAMINER
BRUSCA, J

ART UNIT	PAPER NUMBER
1636	3

DATE MAILED: 01/19/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

FitzGerald

Office Action Summary

Application No.
09/181,027

Applicant(s)
Haaf et al.

Examiner
John S. Brusca

Group Art Unit
1636



☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 40-45 is/are pending in the application.

Of the above, claim(s) 45 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 40-44 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☒ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 1. Claims 40-44, drawn to a Rad51 gene and a tumor suppressor gene, classified in class 536, subclass 23.5.
 2. Claim 45, drawn to a Rad51 protein and a tumor suppressor protein, classified in class 530, subclass 350.

2. The inventions are distinct, each from the other because of the following reasons:

The combination of genes in Group 1 is patentably distinct from the combination of proteins in Group 2 because the two groups are drawn to classes of compounds that are structurally and functionally different.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

4. During a telephone conversation with Dolly Vance on about 1/8/99 a provisional election was made with traverse to prosecute the invention of Group I, claims 40-44.

Affirmation of this election must be made by applicant in replying to this Office action. Claim 45 is withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

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5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Drawings

6. This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

Specification

7. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

8. The disclosure is objected to because of the following informalities:

The disclosure is replete with grammatical and typographical errors, for example at page 51, lines 15-16. The Applicants are requested to carefully review the specification for errors and make appropriate amendments in response to this Office Action. If extensive amendments are required to the specification, a substitute specification that does not include the claims should be filed.

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The specification lists a reference by Haaf, T (1995) on page 58 that could not be located in literature databases. If the reference does not exist, the citation should be corrected or deleted on page 58 and as cited in the specification.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 40-44 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In *In re Wands* (8 USPQ2d 1400 (CAFC 1988)) the CAFC considered the issue of enablement in molecular biology. The CAFC summarized eight factors to be considered in a determination of "undue experimentation". These factors include: (a) the quantity of experimentation necessary; (b) the amount of direction or guidance presented; (c) the presence or absence of working examples; (d) the

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nature of the invention; (e) the state of the prior art; (f) the relative skill of those in the art; (g) the predictability of the art; and (h) the breadth of the claims.

In considering the factors for the instant claims:

a) In order to practice the claimed invention one of skill in the art must use a Rad51 gene combined with a tumor suppressor gene. For the reasons discussed below, there would be an unpredictable amount of experimentation required to use the claimed invention.

b) The specification states on page 26, lines 16-29 that Rad51 may interact with tumor suppressor genes and that a combination of a Rad51 gene and a tumor suppressor gene may be useful in gene therapy treatment and for diagnosis. No further guidance is presented in the specification to use the claimed combination of genes.

c) The specification does not present working examples of using a combination of a Rad51 gene and a tumor suppressor gene.

d) The invention is drawn to a combination of a Rad51 gene and a tumor suppressor gene.

e) Vispe et al. was published before the filing date of the immediate parent Application No. 09/007020, and was received in the STIC library on 3/5/98. Vispe et al. reviews the prior art concerning Rad51, and states that Rad51 is known to bind p53, BRCA1, and BRCA2 proteins. Vispe et al. does not show use of a

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combination of a Rad51 gene and a tumor suppressor gene. Vispe et al. does not show a disease caused by a combined lack of Rad51 and a tumor suppressor. Vispe et al. does not show that a disease may be diagnosed by detecting a combination of Rad51 and tumor suppressor genes or their transcripts.

f) The skill of those in the art of molecular biology is high.

g) The prior art does not predict a way to use the claimed combination of genes.

h) The claims are broad in that they are drawn to a combination of genes for which there is no method of use disclosed in the specification or the prior art.

The skilled practitioner would first turn to the specification for guidance in using the claimed combination of genes. However, the specification does not disclose in any significant detail a method of using the claimed combination of Rad51 and tumor suppressor genes. As such, the skilled practitioner would turn to the prior art for such guidance. However, the prior art does not teach the claimed combination of genes or their method of use. Finally, said practitioner would turn to trial and error experimentation to use the claimed combination of genes without guidance from the specification or the prior art. Such represents undue experimentation.

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 41-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 41-44 are indefinite because they depend from cancelled claim 38. The rejection would be overcome by amending claims 41-44 to depend from claim 40.

For the purpose of examination, the claims have been assumed to incorporate the suggested amendments.

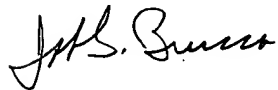
Conclusion

13. Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. For routine submissions the FAX number is (703) 308-4242. For FAX transmissions in cases in which the Examiner has been notified by phone to expect the transmission, the FAX number is (703) 305-7939. In such cases please call the Examiner at (703) 308-4231 at the time of transmission to expedite delivery of the fax. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6 (d)). NOTE: If applicant *does* submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to John S. Brusca, Ph.D. whose telephone number is (703) 308-4231. The examiner can normally be reached on Monday through Friday from 9 AM to 5 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, George Elliott, Ph.D., can be reached at (703) 308-4003.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

A handwritten signature in black ink, appearing to read "John S. Brusca". The signature is written in a cursive, flowing style.

John S. Brusca, Ph.D.

Examiner